

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

A comparison survey of GATA-3, RORyt and FOXP3 genes expression levels in peripheral blood cells of rhinitis patients, before and after treatment with fexofenadine and fluticasone propionate.

Protocol summary

Summary

In this study patients who have clinical sign and symptoms of rhinitis (nasal congestion, rhinorrhea, sneezing, itchy nose, headache, earache, Itchy throat, snoring or postnasal drip), after diagnosis by specialist of allergy, will enter the study. Next, we will make an interview with patients and will explain the situations of the study to patients. If patients Satisfy and desire the study, they will enter the study. From each patient, before treatment and after one month treatment, 5 ml blood will be taken. Treatment will be done in one month by use of anti-histamine (Fexofenadine) and Intranasal corticosteroid (fluticasone propionate). Blood samples will be transferred to CBC vials containing anti coagulant (EDTA) and then will be transferred to the laboratory as quickly as possible. Then, using RNA extraction kit, RNA will be extracted from peripheral blood cells of sample bloods. Next by use of Reverse transcriptase enzyme, the extracted RNA will be transcribed to complementary DNA (cDNA) and then they will be stored in -20 °C until the last step. Then the level of expression of transcription factors gene: GATA-3, Foxp3 and RORyt in all prepared cDNA will be measured, in relative measurement, by use of Real-time PCR and sybergreen method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050233622N2**
Registration date: **2017-07-06, 1396/04/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-06, 1396/04/15

Registrant information

Name

Ali Gorgin Karaji

Name of organization / entity

Kermanshah University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology,
Kermanshah University of Medical Sciences

Expected recruitment start date

2017-05-31, 1396/03/10

Expected recruitment end date

2017-08-03, 1396/05/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison survey of GATA-3, RORyt and FOXP3 genes expression levels in peripheral blood cells of rhinitis patients, before and after treatment with fexofenadine and fluticasone propionate.

Public title

Effect of Fexofenadine and fluticasone propionate on the level of transcription factors: GATA-3, RORyt and FOXP3

in allergic rhinitis patients

Purpose
Basic science

Inclusion/Exclusion criteria
Inclusion criteria: 1- People entering the study should be at the age of 18 to 60 years, 2- They have to study and sign the testimonial before entrance to the study, 3- lack of abnormality in nasal anatomy, 4- having rhinitis symptoms which is confirmed by specialist physician, 5- not being suffered from: asthma, infectious disease, underlying diseases such as diabetes and chronic inflammatory diseases, 6- In addition, pregnant women, people above 65 and those people who suffer from rhinitis because of Senility will not enter the study.
Exclusion criteria: 1- People suffering from infectious diseases or common cold during the period of study, 2- patients taking drugs other than drugs that must consume according to the research plan, during Performance of the project, 3- patients who have a fungal, viral or bacterial disease during the course of study, 4- patients who do not follow the recommended instructions. All these people will be excluded from the study.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, building Number 2 of Kermanshah University of Medical Sciences, Beheshti Boulevard, Kermanshah

City

Kermanshah
Postal code
6714673159
Approval date
2017-03-08, 1395/12/18
Ethics committee reference number
KUMS.REC.1395.756

Health conditions studied

1

Description of health condition studied

Rhinitis patients

ICD-10 code

J30-J31

ICD-10 code description

Vasomotor and allergic rhinitis and Chronic rhinitis, nasopharyngitis and pharyngitis

Primary outcomes

1

Description

RORgt

Timepoint

Before treatment and one month After treatment

Method of measurement

Relative expression of RORgt gene measured by Real-time PCR

2

Description

GATA3

Timepoint

Before treatment and After one month treatment

Method of measurement

Relative expression of GATA3 gene measured by Real-time PCR

3

Description

FOXP3

Timepoint

Before treatment and one month After treatment

Method of measurement

Relative expression of FOXP3 gene measured by Real-time PCR

Secondary outcomes

empty

Intervention groups

1

Description

Drug administration: Fexofenadine: 1 tablet/ day

Fluticasone propionate: one puff nasal spray into each nostril/ day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Kermanshahi Hospital

Full name of responsible person

Dr. Seyed Hamid Reza Mortazavi

Street address

Dr Kermanshahi Hospital, Helal Ahmar Crossroad,
Kermanshah

City

Kermanshah

Full name of responsible person

Ali Gorgin Karaji

Position

University Lecturer (Associate Professor)

Other areas of specialty/work

Street address

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology,
Kermanshah University of Medical Sciences

Full name of responsible person

Koorosh Hamzehee

Street address

Vice Chancellor for Research and Technology,
Building NO. 2 of Kermanshah University of Medical
Sciences, Shahid Beheshti Blv. Kermanshah, Iran

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research and Technology,
Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Medicine, Kermanshah University of Medical
Sciences

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Medicine, Kermanshah University of Medical
Sciences

Full name of responsible person

Ali Gorgin Karaji

Position

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Atefe Mehrmanesh

Position

MSc Student

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty